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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/685,172	10/14/2003	Raghavan Rajagopalan	MRD-62CP	4267

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EXAMINER

HAQ, SHAFIQL

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/685,172	Applicant(s) RAJAGOPALAN ET AL.	
	Examiner Shafiqul Haq	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 2-4, 6, 8-18, 21 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5, 7, 19 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application |
| 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/6/04, 4/25/05</u> | 6) ☐ Other: _____ |

DETAILED ACTION

Response to Election/Restrictions

1. Applicants' election of Group I, claims 1-8, 19 and 20 filed July 12, 2006 in response to Office Action of June 13, 2006 is acknowledged and entered. Applicants' election of a composition A and election of Dye=cyanines, X= a single bond, Y=hydrogen, E= bombesin receptor binding molecule, R¹ and R⁸-R⁹= hydrogen and L= -(CH₂)_a- wherein a= 0 is also acknowledged. Claims 1, 5, 7 and 19-20 are readable on the elected species. Since the election is made without traverse, the restriction requirement is deemed proper and is made FINAL.

Accordingly, claims 2-4, 6, 8-18 and 21-22 are withdrawn from further consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03. Examiner suggests that the non-elected claims cited supra be canceled in response to this Office action to expedite prosecution.

2. Claims 1, 5, 7 and 19-20 are examined on merits.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 5 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the phrase "the composition of claim 1 comprising at least two of formula 1. It is unclear whether the term "at least two of formula 1" is intended to

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mean same of different compounds (i.e. same of different species of compound of formula 1). It is also unclear whether "at least two of formula 1" is linked to each other i.e. arrangement of at least two compound of formula 1 in the composition is unclear.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Cacak et al. (US 3,887,379).

Clecak et al describe photoactive azide-substituted dye compounds which correspond to the compound of formula 1 of instant claim 1 wherein Dye=cyanines, X= a single bond, Y=hydrogen, E= H, and L= $-(CH_2)_a-$ wherein a= 0. See Clecak et al: Examples I, III, and IV. These compounds anticipate the compounds of instant claim 1.

7. Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Leung et al. (US 6,004,536).

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Leung et al describe compounds which correspond to the compound of formula 1 of instant claim 1 wherein Dye=cyanines, X= a single bond, Y=hydrogen, E= H, and L= $-(CH_2)_a-$ wherein a= 0.. See the azide-terminated dyes depicted by the formula of col.4, line 20; col. 5, lines 45-53; col. 6, lines 10-27, and col. 16, lines 14-24. These compounds anticipate the compounds of formula 1 of instant claim 1.

8. Claims 1 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Achilefu et al. (US 6,217,848 B1).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Achilefu et al describe photoactive azide-substituted dye compounds which correspond to the compound of formula 2 of instant claim 1 wherein Dye=cyanines, X= a single bond, Y=hydrogen and E= bombesin receptor binding molecules. See Achilefu et al: compounds of formula 1 and formula 2 of columns 2-3. Bioactive peptides (e.g. bombesin, neurotensin, cholecystokinin) are linked to cyanine dye through a large number of linkers (columns 2-4 especially, column 5, lines 5-10) and at least one of them anticipate the compound of formula 2 of instant claim 1 and 20.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Edelman (4,818,684) in view of Ulman et al. (3,996,345).

Present application disclose a photoactive composition comprising at least one compound of formula E-L-DYE-X-Y (Formula 2). This formula reads of a dye bound to E (E-DYE) (i.e. receptor binding molecules bound to a DYE) when X= a single bond, Y=hydrogen, E= H, and L= $-(CH_2)_a-$ wherein $a= 0$.

Edelman et al teach an anti-Ig Ab designated 8 GII-C6 which is secreted by hybridoma HB 8708. This antibody binds a glucocorticoid receptor (i.e. steroid receptor binding molecules). See col.9, lines 11-17. This antibody is claimed in a form of being detectably labeled with a fluorescent moiety bound to the antibody (claim 11).

Edelman et al do not recite specific fluorescent dyes.

Ullman et al teach numerous known fluorescent dyes at col.8, lines 1-35. These include fluoresceine, rhodamines and cyanines. These dyes are taught as being conjugated to antibodies (e.g. examples II and III). Hence the labels recited in instant claim 34 would have been obvious as species of the fluorescent moiety taught by Edelman et al.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5, 7 and 19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of copending Application No. 10/776,840. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-10 of referenced U.S. Patent Application are drawn to azide substituted photoactive compound that are structurally similar. See general formula E-L-DYE-X-N₃ of claim 1 of copending application wherein definition of DYE, E, L and X reads on the definition of DYE, E, L and X of present application.

The compounds in referenced U.S. Patent Application differ from the present compound only by having aromatic or heteroaromatic radical in the definition of DYE in copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Wang et al (US 6,686,209 B2) disclose cannabinol linked to tracer at position 1 through different linker (Fig.4 and column 4, lines 10-24).

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

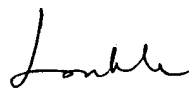
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SHAFIQUL HAQ
EXAMINER
ART UNIT 1641



LONG V. LE
SUPERVISORY PATENT EXAMINER
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01/15/06